guidelines used in clinical research: The Cochrane Reviewer's Handbook and a guideline prepared by the The Australian National Health and Medical Research Council. The aim of the guideline was to introduce the main concepts through a language that is more simple and accessible to health care professionals, familiar or not with the methodology of systematic reviews and meta-analyses. This guideline covers the three phases of a SR: planning, production and reporting of the SR. It does not take into account the impact of the type of question in the review process and does not exhaust all the mechanisms necessary in order to understand and perform a meta-analysis. It also presents the detailing of some fundamental concepts needed to conduct the systematic review in the form of appendices. In 2011, it was given the first version of the guideline. DECIT was responsible for the review and publishing of the final document. In 2012, the first issue of the guideline was published. The importance of the guideline is to orient and standardize the preparation and production of a quality SR, mainly due to the gap that exists in the national literature.

PRM152

COLLECTING PROS IN PATIENT REGISTRIES: THE NEED FOR AND POTENTIAL IMPACT OF PROVIDING PRO DATA TO THE TREATING PHYSICIAN – AND WHEN

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The advent of ePROs and direct-to-patient reporting has enabled patients participating in registries to report their symptom or treatment experiences between physician visits, with minimal patient burden. These independent reporting approaches are often used to support patient retention over long follow-up periods, and/or to collect patient-reported data outside of typical physician visit schedules. When a patient completes PROs independent of a physician's presence (i.e., not completed at the physician's office and not entered by the registry site), the treating physician may not be aware of the patient's responses and may need to either proactively ask for this information or wait to obtain this information at the end of the study. The move toward independent reporting of PRO data introduces several competing concerns. First, physician knowledge of the PRO responses could potentially alter the naturalistic follow-up in an observational study, if, for example, the physician's knowledge of the PRO response prompts him/her to alter the patient's treatment. As a result, patient reporting independence may be preferred from a research purity perspective. However, any PRO response that may be a safety signal would carry ethical considerations; in such a case, reporting independence would not be preferred. If patient care is always paramount to the benefits of research, then it could be argued that the optimization of patient care is only possible when the physician has all available patient information (e.g., PROs) at his/her disposal, in as close to real-time as possible. In addition, some research indicates that patients are more likely to complete PROs when their physician is aware of and using the PRO data to inform treatment decisions. Further discussion will focus on sponsor and researcher responsibilities for funneling observed data on a patient's experience back to the treating physician, drawing on examples from the literature and registry protocols.

PRM153

PRACTICAL APPROACHES TO ACHIEVING REAL-WORLD STUDY DATA REPRESENTATIVE OF THE TARGET POPULATION

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PURPOSE: To describe the most effective approaches to achieving a real-world study data sample that is representative of the target population. **DESCRIPTION:** Considerable attention is paid to the design and analysis of outcomes research studies to address internal validity by minimizing bias and confounding. However, too often, study sample populations are simply assumed to be representative of the study populations from which they are drawn, or are assessed for their representativeness only after the study has been conducted. Ideally, sample estimates should be as close as possible to their population value in order to make inferences about that study population. Practical implementation of measures to avoid selection bias and ensure a robust sampling procedure can be problematic. Challenges include, willingness of sites and patients to participate in research (convenience sampling), and management of site and patient drop-out after the study has begun. While many database studies and patient registries carry very large sample sizes and therefore begin to approximate the target population simply by means of sheer size, smaller studies may need to take steps, through stratified sampling and enrollment caps, to ensure that the study sample is reflective of the target population. These stratification variables may be at the site level (e.g., physician specialty, geography), the patient level (age, gender, ethnicity, disease duration) or both. Temporal issues may also be problematic where studies performed in the past may not reflect rapid changes impacting today's target population. Following a brief overview of the design and analysis considerations, this presentation will focus on case examples, drawn from different organizations, of approaches to achieving a representative sample, highlighting some of the challenges intrinsic to real-world research. Best practice recommendations will be provided to guide researchers on the most effective approaches, including the use of reference populations within specific countries.

PRM154

UTILIZATION OF UNMANNED AIRCRAFT SYSTEMS (UAS) FOR EMERGENCY MEDICAL SITUATIONS IN RURAL COMMUNITIES: A VISION FOR THE FUTURE

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OBJECTIVE: We propose a paradigm and ranking system for potential medical applications of unmanned aircraft systems (collectively UAS). Over the past three decades, UAS have become a vital component to our armed forces, used notably for combat but also commonly used for work in intelligence, reconnaissance and surveillance data collection. Such are defined as an aircraft without a human pilot on board, operated either autonomously by computer or under remote control by a human pilot. **METHODS:** We performed a targeted literature search for medical applications of UAS and rank-ordered strengths and weaknesses according to emerging applications and corresponding difficulty, feasibility and cost. **RESULTS:** Based on secondary sources, we report conceptual factors that can contribute to the practicality and efficiency of UAS in emergency medical situations. These were 1) frequency of occurrence, 2) time-sensitivity of occurrence, 3) rurality and complex terrain, 4) financial impact and 5) cultural acceptance. The results of our matrix point to a gradation of accepted uses for UAS with the variance in geographical location and urgency directly relating to an increase in operation costs. It is well known that natural disasters are increasing in frequency and intensity. Salient platforms for using UAS in medical delivery would be in the areas of natural and combative disaster relief. During these occurrences the use of UAS to aid in the medical relief could be a great asset. **CONCLUSION:** Our model illustrates how Big Data can be leveraged to improve ongoing quality and efficiency of UAS-delivered medical supplies, reduce time for delivery of supplies during times of natural disasters, and thus eschew our reliance on manned aircraft to assist in critical and non-critical medical operations.

PRM156

PUBLICATION MANUAL OF BUDGET IMPACT ANALYSIS (BIA) BY THE DEPARTMENT OF SCIENCE AND TECHNOLOGY OF THE MINISTRY OF HEALTH (DECIT)

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The epidemiological and economic methods applied to health technologies evaluations had a significant development in the last two decades. The need to balance the incorporation of new technologies in health care and limited financial resources promoted the construction and application of instruments supporting the decision making of health technology. The requirement Budget Impact Analysis formally stated in Law 12.401/2011 establishing the incorporation process technologies in SUS. In this context, in 2010/2011, the National Agency of Sanitary Surveillance (ANVISA) and DECIT, in partnership Institute for Health Technology Assessment (IATS) for drawing up of this guideline. In the first stage of development were used international recommendations of Canada, Australia, the UK and Poland, the recommendations of the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) and the methods used in studies of budgetary impact that had already been published. Afterwards, drafted a preliminary version of the Guideline and a standard tool - Excel worksheets - to estimate the uptake of monetary resources required for adoption of new technologies. Revisions were carried out by technicians DECIT and health agencies, and the proposal was submitted to the Working Group on Development of Methodology REBRATS, composed of experts and academic researchers from several Brazilian states. Were also carried out workshops for the application of spreadsheets. In 2012, the first edition of the Guidelines was published two thousand copies in Portuguese in order to provide best practice recommendations for studies of budget impact.

PRM157

MIXED METHODS FOR THE DEVELOPMENT OF CLINCIAL OUTCOME ASSESSMENTS (COAS): EXPLORING FURTHER POSSIBILITIES FOR MIXED DATA COLLECTION AND ANALYSIS

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Mixed methods are fast becoming the go-to methodology for the development and validation of clinical outcome assessments (COAs). Although mixed methods have become popularized for COA development, most of this attention has focussed on Rasch measurement theory (RMT). However, the potential utility of mixed methods in COA development goes beyond RMT. There is a well-established literature base exploring the use of mixed data collection and crossover analyses in social research and many of these approaches can be readily applied to COA development. Thus a toolkit of methods is proposed which can be pragmatically selected to support the development of interpretable and purposeful COAs. Further integration of qualitative and quantitative data throughout the COA development process can serve to continually test the evolving hypothesis of the measurement construct and aid in evidence triangulation. Data can be transformed to create new data through 'quantitizing' qualitative data and 'qualitizing' quantitative data. Qualitative data collected during concept elicitation can be converted into binary code allowing development of inter- and intra-respondent matrices to explore the frequency and intensity of concepts. These data can be subjected to factor, correlational and regression analyses to explore the hierarchical structure and inter-relationships of qualitatively-derived themes and variables. Concept mapping techniques also allow the translation of qualitative data into pictorial form to show "clusters" of, or inter-relationships between, concepts. This collaborative approach involves stakeholders as partners in the research to generate, sort and rate items into conceptual models using statistical analyses. There are exciting opportunities to build upon existing practice and advance mixed research approaches in the field of COA development. Integrating mixed data collection and crossover analyses can enhance the interpretability and purposefulness of COAs ensuring they are developed with an evolving hypothesis and fit for purpose. The application of such methods for regulatory COA development requires further exploration.

PRM158

SIMULTANEOUS ITEM DEVELOPMENT (SID) FOR CLINICAL OUTCOMES ASSESSMENTS (COAS)

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